REMARKS

In the Office Action dated December 18, 2008, claims 2-10 and 12 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. In response, independent claim 12 has been amended to include numerous limitations therein that clearly cause claim 12 to be "tied to a machine" and/or make claim 12 "machine implementable," in conformance with the recent decision of the United States Court of Appeals for the Federal Circuit in *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q. 2d 1385 (2008), *en banc*. Editorial changes have been made in the dependent claims consistent with the changes to independent claim 12.

All claims are therefore submitted to constitute statutory subject matter in compliance with 35 U.S.C. §101.

Claims 2-10 and 12 additionally were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner referred to the language in claim 12 of "generating a customized input platform that includes a collection of input fields configured only and precisely for entry of the data that is necessary for the specific medical study," and the Examiner stated he is interpreting "only and precisely" to modify the configuration of the input fields for data entry, or specifically how the data is being entered.

The Examiner cited paragraph [0013] in the pre-grant publication, and stated the specification does not define "type of the data" and therefore the Examiner understands that the "type of the data" is text. Applicants submit this is an unjustifiably narrow interpretation of the word "type" as used in paragraph [0013]. The word "type", as is clear from the context, was being used in a much more general sense as meaning "informational content." It would be trivial, and therefore

meaningless, in this context to interpret "type" as being a statement that the data entered are text data, because it is of course the case that data entered in a clinical study must be formulated as text data, and therefore there would be no need to make such a statement if it was only intended to be understood as meaning that text data must be entered.

More importantly, however, Applicants fail to see any relevance of the interpretation of the word "type" in paragraph [0013] of the specification with respect to compliance of the aforementioned language of claim 12 with Section 112, first paragraph. The Examiner is correct that the phrase "only and precisely" modifies the configuration of the input fields for data entry, and this is clearly understandable as meaning that those input fields will be specifically configured, dependent on the specific clinical study in question, so that data that are not needed, permitted or relevant to that particular study will not be entered, because no input field is provided for such unneeded, unwanted or superfluous data. Applicants submit this is the plain and ordinary meaning of the input fields being "only and specifically" configured for entry of data that is necessary for the specific medical study.

Moreover, Applicants submit that, to the extent that the Examiner believes paragraph [0013] of the present specification means that this phrase in claim 12 must be interpreted as meaning that the input fields are configured only for entry of text data, Applicants submit this is not a reasonable interpretation of the language of claim 12, and therefore would be contrary to the rules for standard claim interpretation that must be employed when examining a patent claim. Interpreting claim 12 in the manner proposed by the Examiner (if the Examiner is, in fact, proposing such an interpretation), would trivialize the language of claim 12 and

render it virtually meaningless in the present context. When an alternative interpretation is available that avoids ascribing such a trivial and meaningless definition of a claim term, it must be assumed that the Applicants did not intend the trivial and meaningless definition as long as a more meaningful and relevant definition/interpretation is disclosed in the specification.

Applicants therefore respectfully submit that claims 2-10 and 12 are in full compliance with all provisions of Section 112, first paragraph.

Claims 2-10 and 12 also were rejected for the same reasons under 35 U.S.C. §112, second paragraph because the Examiner stated the term "only and precisely" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As noted above, the term "only and precisely" is only one portion of the overall phrase of "only and precisely" for entry of the data that is necessary for the specific medical study." A person of ordinary skill in the field of implementing medical studies using electronic data entry would have no difficulty in understanding what data are necessary for a specific medical study, and therefore would have no difficulty in understanding, in turn, the scope and meaning of input fields that are configured only and precisely for entry of that data. It is the data that are necessary for a specific medical study that, in turn, will define the scope of "input fields configured only and precisely" for entry of that data.

Claims 2-10 and 12 are therefore submitted to be in full compliance of all provisions of Section 112, first paragraph.

Claim 12 is rejected under 35 U.S.C. §102(b) as being anticipated by Official Notice. At page 2 of the Office Action, the Examiner noted that Applicants are now deemed to have admitted the Official Notice that was previously taken that a clinical trial administrator and the research entity commissioning a clinical study can be the same. Applicants have never disagreed that this possibility exists, but if this is the same "Official Notice" that the Examiner is now using as a basis for a completely anticipation of claim 12, Applicants submit this is not only going far beyond anything encompassed by the *facts* of the aforementioned Official Notice, but also is an abuse of the practice of taking Official Notice.

The purpose of permitting an Examiner to take Official Notice of one or more facts is to relieve the Examiner from having to conduct searching to substantiate the presence of such facts or knowledge in the prior art. Since a patent claim necessarily encompassed multiple facts, it is not considered to be within the scope of taking Official Notice to reject an entire claim based on taking notice of one fact. Moreover, if the Official Notice on which the Examiner is relying for rejecting claim 12 is the aforementioned knowledge that a clinical trial administrator and the research entity commissioning the study can be the same, Applicants fail to see how this single piece of knowledge can justify anticipation of the entirety of claim 12, which necessarily requires that each and every claim limitation be found in the prior art.

If the Examiner is taking "Official Notice" that the previous language of claim 12 could (allegedly) be implemented using a piece of paper, Applicants respectfully submit this is the Examiner's *opinion*, but is not a *fact* of which the Examiner is permitted to take Official Notice. Nevertheless, Applicants submit that the

amendments that have now been made to independent claim 12 make this issue moot.

Applicants therefore submit that claim 12 is not anticipated by "Official Notice" and further traverse the Examiner's alleged statutory authority for even making a rejection of that type.

Claims 12 and 9 were rejected under 35 U.S.C. §102(e) as being anticipated by Tkaczyk et al.

This rejection is respectfully traversed for the following reasons.

This is the same rejection that was made in the Office Action dated July 25, 2008, wherein Applicants identified a number of elements of claim 12 that are not disclosed or suggested in the Tkaczyk et al. reference. The Examiner did not respond to any of those statements by the Applicants, but merely stated that "one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references." Applicants of course agree with this statement, but it is of course unavoidable to respond to an anticipation rejection by discussing an individual reference, since an anticipation must necessarily be based only on an individual reference. When the Examiner then makes obviousness rejections of dependent claims, by adding secondary references to the same reference that was used as the basis for the anticipation rejection, the same arguments that were made with regard to the primary reference in the context of the anticipation rejection are clearly relevant to the obviousness rejection. If the Examiner relied on one of the secondary references as having an impact on the basis for rejecting the independent claim, it would be a different matter. Where the Examiner relies on the secondary references only for the purpose of (allegedly)

locating the subject matter of a dependent claim 1, and then simply "tax on" the teachings of that secondary reference to the teachings of the primary reference that was used for anticipation, it is clearly proper to reference the arguments made with regard to the primary reference in the context of the anticipation rejection.

As noted in Applicants' previous response, in the Tkaczyk et al. reference, there is no disclosure whatsoever of generating a template in a customized manner so that the template has input fields (i.e., a "collection of input fields") configured only and precisely for entry of data for a specific medical clinical study. None of the paragraphs in the Tkaczyk et al. reference cited by the Examiner provide information as to how the template itself is generated, and without such a specific disclosure, a person of ordinary skill in the field of collecting clinical study data reading the Tkaczyk et al. reference would assume that the templates are merely generic templates, and have no specific application or relation to any individual medial clinical study.

The Tkaczyk et al. reference therefore does not solve the problem of the use of such "generic" templates for entering data at numerous locations for collection for use in a clinical study. As explained in the introductory portion of the present specification, it is a problem in the collection of data for a clinical study that, because the data must necessarily be obtained and entered at a number of disparate locations that are separated from each other, the data entry at the different locations, if only "generic" data entry forms are used that are applicable to any number of different types of clinical studies, the data will not be uniformly entered for the particular clinical study in question. Those generic forms, in order to be generic, must necessarily include input fields broad enough to encompass many different

type of clinical studies, and therefore are prone to unnecessary or superfluous data being entered, or causing the person entering the data to make his or her own judgments as to which data should be entered into which input field.

This problem is solved in accordance with the present invention by the use of an input program platform that is specifically customized to provide a collection of input fields configured only and precisely for entry of data for the particular medical clinical study in question, i.e., the particular medical clinical study for which the input platform has been designed (customized).

No such method is disclosed in the Tkaczyk et al. reference. Therefore, neither claims 12 or 9 is anticipated by that reference.

Claims 2-8 were rejected under 35 U.S.C. §103(a) as being anticipated by Tkaczyk et al. in view of Teshima. As noted in Applicants' previous response, however, in substantiating this rejection, after discussing claims 2, 3 and 4, the Examiner then switched to reliance on the Thangaraj reference. The Thangaraj et al reference, however, was relied on only with regard to claim 10, as substantiating a rejection under 35 U.S.C. §103(a) in combination with Tkaczyk et al. The Examiner did not correct or clarify the rejection of claims 2-8 in the December 8, 2008 Office Action.

Nevertheless, as before, all of these rejections under 35 U.S.C. §103(a) are respectfully traversed for the reasons discussed above in connection with the anticipation rejection based on Tkaczyk et al. Since the Tkaczyk et al. reference does not disclose the subject matter of claim 12, and since the Teshima and Thangaraj references were cited by the Examiner only for the purpose of providing details of certain of the dependent claims, the arguments above concerning the

Tkaczyk et al. reference are equally applicable to these rejections under Section 103(a).

All claims of the application are therefore submitted to be in condition for allowance, and early consideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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